

## PCT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
 US Department of Commerce  
 United States Patent and Trademark  
 Office, PCT  
 2011 South Clark Place Room  
 CP2/5C24  
 Arlington, VA 22202  
 ETATS-UNIS D'AMERIQUE  
 in its capacity as elected Office

Date of mailing (day/month/year) 19 June 2001 (19.06.01)	
International application No. PCT/GB00/03273	Applicant's or agent's file reference P24394B/RMC
International filing date (day/month/year) 25 August 2000 (25.08.00)	Priority date (day/month/year) 26 August 1999 (26.08.99)
Applicant NASHEF, Aws et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
 22 March 2001 (22.03.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	Authorized officer  Olivia TEFY  Telephone No.: (41-22) 338.83.38
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P<sup>A</sup>TENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

MURGITROYD & COMPANY  
373 Scotland Street  
Glasgow G5 8QA  
ROYAUME-UNI

Date of mailing (day/month/year) 04 juillet 2001 (04.07.01)	<b>IMPORTANT NOTIFICATION</b>  International filing date (day/month/year) 25 août 2000 (25.08.00)
Applicant's or agent's file reference P24394B/LLO	
International application No. PCT/GB00/03273	

## 1. The following indications appeared on record concerning:

☒ the applicant      ☒ the inventor      ☐ the agent      ☐ the common representative

## Name and Address

WIEDE, Ted, Vander  
5 Flemington Court  
Strathaven M40 6FL  
United Kingdom

## State of Nationality

US

## State of Residence

GB

Telephone No.

Facsimile No.

Teleprinter No.

## 2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person      ☐ the name      ☒ the address      ☐ the nationality      ☐ the residence

## Name and Address

WIEDE, Ted, Vander  
5 Flemington Court  
Strathaven ML10 6FL  
United Kingdom

## State of Nationality

US

## State of Residence

GB

Telephone No.

Facsimile No.

Teleprinter No.

## 3. Further observations, if necessary:

## 4. A copy of this notification has been sent to:

<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input checked="" type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	Authorized officer  R. Chrem  Telephone No.: (41-22) 338.83.38
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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>P24394B/RMC</b>	<b>FOR FURTHER ACTION</b> <small>see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.</small>	
International application No. <b>PCT/ GB 00/ 03273</b>	International filing date (day/month/year) <b>25/08/2000</b>	(Earliest) Priority Date (day/month/year) <b>26/08/1999</b>
Applicant  <b>AORTECH INTERNATIONAL PLC</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☒ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1

☐ None of the figures.

## Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

A catheter having a heat transfer device at or near its distal end, wherein the heat transfer device is layered or coated onto or into the catheter wall is described. The heat transfer device is preferably a flexible film having one or more electrical resistor flow paths thereon or therethrough, or is disposed directly onto the catheter wall by a deposition process. The heat transfer device may alternatively be formed by a length of the catheter wall being formed wholly, substantially or partly from doped material able to act as a heat transfer device upon application of power therethrough. The heat transfer device is preferably powered by one or more metal wires co-extruded within the catheter body.

# INTERNATIO SEARCH REPORT

International application No.  
PCT/GB 00/03273

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
  
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
  
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
  
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
  
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-18

A catheter having a heat transfer device near its distal end, wherein the heat transfer device is layered or coated onto the catheter wall.

2. Claims: 19-28

A catheter having one or more metal wires through the catheter wall.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/03273

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61B18/08

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 720 775 A (LARNARD DONALD J) 24 February 1998 (1998-02-24)	1-3, 5-9, 16-18
Y	column 3, line 11 -column 5, line 18; figures	25
A	US 5 509 424 A (AL-ALI AMMAR) 23 April 1996 (1996-04-23) cited in the application column 4, paragraph 54 -column 7, paragraph 47; figures	1, 7, 12-14
A	US 5 380 320 A (MORRIS JAMES R) 10 January 1995 (1995-01-10) abstract; figures	1, 14, 15
A	US 5 921 924 A (AVITALL BOAZ) 13 July 1999 (1999-07-13) claim 8; figures	1, 7, 8
	--- -/--	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*&\* document member of the same patent family

Date of the actual completion of the international search

16 January 2001

Date of mailing of the international search report

23. 01 2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Kousouretas, I

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/03273

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 865 801 A (HOUSER RUSSELL A) 2 February 1999 (1999-02-02) abstract; figures ---	1
X	US 5 247 136 A (MITSUYASU KAZUYUKI ET AL) 21 September 1993 (1993-09-21) column 3, line 4 -column 5, line 9; figures ---	19-22, 24,26-28 25
Y		
X	US 5 364 357 A (AASE BRENDA L) 15 November 1994 (1994-11-15) column 3, line 54 -column 4, line 20; figures -----	19,22,24



# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/03273

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5720775	A	24-02-1998	NONE		
US 5509424	A	23-04-1996	NONE		
US 5380320	A	10-01-1995	NONE		
US 5921924	A	13-07-1999	US	5687723 A	18-11-1997
			US	5487385 A	30-01-1996
			US	6138043 A	24-10-2000
			US	5730127 A	24-03-1998
			US	5842984 A	01-12-1998
			AU	685559 B	22-01-1998
			AU	1265495 A	19-06-1995
			CA	2177982 A	08-06-1995
			EP	0731665 A	18-09-1996
			JP	9506017 T	17-06-1997
			WO	9515115 A	08-06-1995
US 5865801	A	02-02-1999	AU	5669796 A	18-02-1997
			WO	9703604 A	06-02-1997
US 5247136	A	21-09-1993	JP	4106813 A	08-04-1992
US 5364357	A	15-11-1994	AT	104560 T	15-05-1994
			AU	621008 B	27-02-1992
			AU	6317790 A	28-03-1991
			CA	2025961 A,C	26-03-1991
			DE	9013331 U	31-10-1990
			DE	69008290 D	26-05-1994
			DE	69008290 T	04-08-1994
			DK	420486 T	24-05-1994
			EP	0420486 A	03-04-1991
			ES	2050963 T	01-06-1994
			IE	64488 B	09-08-1995
			JP	3205062 A	06-09-1991
			NO	178425 B	18-12-1995

## PATENT COOPERATION TREATY



## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

RECEIVED 21 MAR 2002

PCT

Applicant's or agent's file reference P24394B/LLO/GST		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/03273	International filing date (day/month/year) 25/08/2000	Priority date (day/month/year) 26/08/1999	
International Patent Classification (IPC) or national classification and IPC A61B18/08			
Applicant AORTECH INTERNATIONAL PLC			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"><li>I <input checked="" type="checkbox"/> Basis of the report</li><li>II <input type="checkbox"/> Priority</li><li>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li><li>IV <input checked="" type="checkbox"/> Lack of unity of invention</li><li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li><li>VI <input type="checkbox"/> Certain documents cited</li><li>VII <input type="checkbox"/> Certain defects in the international application</li><li>VIII <input type="checkbox"/> Certain observations on the international application</li></ul>			
Date of submission of the demand 22/03/2001		Date of completion of this report 19.03.2002	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Schoeffmann, H Telephone No. +49 89 2399 2625 	

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03273

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, pages:**

1-11 as originally filed

**Claims, No.:**

1-28 as originally filed

**Drawings, sheets:**

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB00/03273

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.  
☐ paid additional fees.  
☐ paid additional fees under protest.  
☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.  
☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.  
☒ the parts relating to claims Nos. 1-18.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes:	Claims 12-15
	No:	Claims 1-11, 16-18
Inventive step (IS)	Yes:	Claims
	No:	Claims 12-15

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/GB00/03273**

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Industrial applicability (IA)    Yes:    Claims    1-18  
   No:    Claims

2. Citations and explanations  
   **see separate sheet**

**Section IV:**

1. The current application pertains to two inventions not so linked as to form a general common inventive concept.
  - (i) Claims 1-18 relate to a catheter with a heat transfer device layered or coated onto or into the catheter wall;
  - (ii) Claims 19-28 relate to a catheter the wall of which has one or more metal wires therethrough;

Since catheters are generally known (see eg. D1 identified below) the claims have no common technical feature which distinguishes them over D1.

**Section V:**

1. Reference is hereinafter made to the following documents:

D1....US-A-5 720 775

D3....US-A-5 921 924

D4....US-A-5 509 424

D5... US-A-5 380 320

2. D1 discloses a percutaneous ablation catheter (cf. abstract) with an electrode (cf. fig.3,4: reference numeral (15)) near its distal end, the electrodes serves as a heat transfer device and it is layered or coated onto the catheter wall (cf. col.3, lines 11-22). Claim 1 thus lacks novelty so that the requirement of Art.33(2) PCT is no met.
3. Document D1 also discloses the additional features of the dependent

claims 2-8 and 16-18 so that in combination with the claims to which they refer no novel subject-matter is defined (Art.33(2) PCT):

claims 2,3:

see col.4, the paragraph about lines 28-37: the film is malleable, and forms at least one resistor path with decreased impedance (cf. also col.5, lines 30-32 et seq.), the film is located around the catheter wall, as shown in figs.3,4. Thereby one electrical path has been created;

claims 4,5,7,8:

according to D1, the conductive layer is vapour deposited onto the polymer catheter shaft (col.4, lines 56-63), it is thus added onto a plastic backing, ie. the catheter wall (cf. also col.5, lines 12-15)

claim 6: coating process, see D1, col.6, lines 13-21;

claims 16-18:

an outer gold or silver layer, see D1, col.6, lines 13-20 and the table in col.5;

4. As regards the dependent claims 9-11 reference may be had to document D3. D3 also relates to ablation catheters (col.1, lines 15-19) with a heat transfer device at their distal end (cf. fig.1, reference numeral (32) and col.7, lines 35-39), the heat transfer device being layered or coated onto or into the catheter wall (cf. col.14, lines 6-11). As regards the additional features of claims 10 and 11, see D3, col.14, line 8. Claims 9-11 thus also lacks novelty with respect to D3 so that the requirement of Art.33(2) PCT is not met.
5. The additional features as of claims 12-15 are obvious in the context of catheters and are merely used for their known purpose. Since no unexpected or unforeseeable technical effect is achieved, these claims fail to define inventive subject-matter and the requirement of Art.33(3) PCT is not met.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB00/03273

claims 12, 13: temperature sensors, see D4, col.5, lines 30-36;

claims 14,15:

an insulator layer such as parylene C and reasons for applying it, see D5,  
col.2, lines 45-57;



(19) World Intellectual Property Organization  
International Bureau



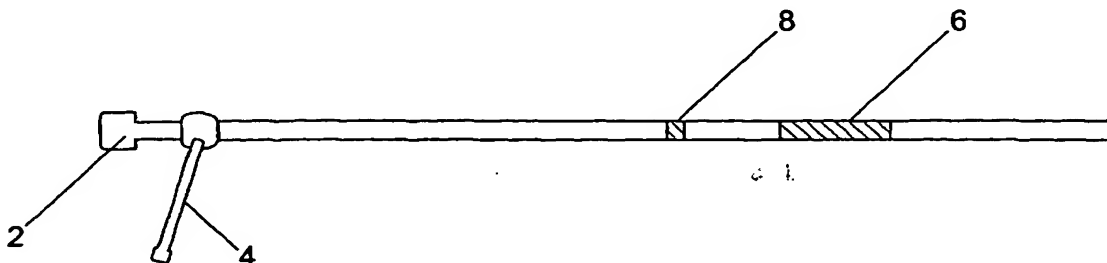
(43) International Publication Date  
1 March 2001 (01.03.2001)

PCT

(10) International Publication Number  
**WO 01/13808 A1**

- (51) International Patent Classification<sup>7</sup>: **A61B 18/08**
- (21) International Application Number: **PCT/GB00/03273**
- (22) International Filing Date: **25 August 2000 (25.08.2000)**
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:  
9920112.1 26 August 1999 (26.08.1999) GB  
60/153,414 10 September 1999 (10.09.1999) US
- (71) Applicant (for all designated States except US):  
**AORTECH INTERNATIONAL PLC [GB/GB];**  
Phoenix Crescent, Strathclyde Business Park, Bellshill  
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- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **NASHEF, Aws**  
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Court, Strathaven M40 6FL (GB). **MCNAIR, Robert**  
[GB/GB]; Flat 2/1, 93 Stranmore Road, Mount Florida,  
Glasgow G42 9AL (GB). **WILSON, Stephen** [GB/GB];  
63 Drum Crescent, Gilmorton, Edinburgh EH17 7EB  
(GB). **ANDREWS, Simon** [GB/GB]; 24 Loudon Hill  
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- (74) Agent: **MURGITROYD & COMPANY; 373 Scotland**  
Street, Glasgow G5 8QA (GB).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU,  
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ,  
DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR,  
HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR,  
LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ,  
NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM,  
TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian  
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European  
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,  
IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG,  
CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:**  
— With international search report.  
— Before the expiration of the time limit for amending the  
claims and to be republished in the event of receipt of  
amendments.
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: **HEAT TRANSFER DEVICES**



(57) Abstract: A catheter having a heat transfer device at or near its distal end, wherein the heat transfer device is layered or coated onto or into the catheter wall is described. The heat transfer device is preferably a flexible film having one or more electrical resistor flow paths thereon or therethrough, or is disposed directly onto the catheter wall by a deposition process. The heat transfer device may alternatively be formed by a length of the catheter wall being formed wholly, substantially or partly from doped material able to act as a heat transfer device upon application of power therethrough. The heat transfer device is preferably powered by one or more metal wires co-extruded within the catheter body.

WO 01/13808 A1

1     **"HEAT TRANSFER DEVICES"**

2

3     The present invention relates to improvements for  
4     catheters having a heat transfer device at or near  
5     their distal end.

6

7     One of the present constraints concerning manufacture  
8     of catheters designed to monitor various cardiac  
9     output data is the manner and form of the required  
10    heat transfer device system. One present form of  
11    heat transfer device involves a thermal coil radially  
12    disposed about the catheter body to form a generally  
13    tubular coil which extends along the outside wall of  
14    the catheter. Such a heat transfer device is shown  
15    in US 5509424. However, such heat transfer coils  
16    require time and effort to wind and form and also  
17    restrict the possible miniaturisation of such  
18    catheters for use in paediatrics.

19

1 It is an object of the present invention to provide  
2 improvements to the manner and nature of heat  
3 transfer devices for use with catheters.  
4

5 Thus, according to one aspect of the present  
6 invention, there is provided a catheter having a heat  
7 transfer device at or near its distal end, wherein  
8 the heat transfer device is layered or coated onto or  
9 into the catheter wall.

10

11 In one embodiment, the heat transfer device is a  
12 flexible film having one or more electrical resistor  
13 flow paths thereon or therethrough, which film is  
14 locatable around the catheter wall.

15

16 Such films can include flexible metal films on which  
17 one or more electrical paths have been etched or  
18 otherwise created. Alternatively, one or more  
19 electrical paths could be added onto a plastic film  
20 backing. The form of addition includes any type of  
21 deposition or coating, and the one or more electrical  
22 paths could be formed by etching, etc to form the  
23 resistor structure.

24

25 One or more temperature sensors or sensor leads could  
26 be included on or within the heat transfer device  
27 film to monitor the temperature of the electrical  
28 path(s), and thus the temperature of the overall heat  
29 transfer device.

30

1     Suitable backing materials include PVC, polyurethane,  
2     silk, synthetic silk, silicon rubber, Elaston™ etc,  
3     possibly about 20-80 microns thick, and suitable thin  
4     high resistant metal films include nickel, chromium  
5     or nickel-chromium. These can be deposited on the  
6     plastic backing material, and patterned using a  
7     photolithography mask to form the resistor structure.

8  
9     On top of the resistor structure could be located a  
10    suitable insulator like parylene C, followed by  
11    deposition of a suitable temperature sensing means  
12    e.g. thermistors or platinum. Finally the outer  
13    surface may be coated with a silver or gold layer,  
14    possibly 5-10 microns thick. This layer assists in  
15    averaging heat distribution. Gold and/or silver are  
16    suitable as they are conductive and biocompatible.  
17    Optionally a further layer of parlyene C or other  
18    insulation is added as the outer layer.

19  
20    Possible arrangements for the electrical paths and  
21    temperature sensing means across the backing material  
22    are shown in Figures 3 and 4 of the accompanying  
23    drawings.

24  
25    This form of heat transfer device can be fixed around  
26    a catheter at or near its distal end. Preferably the  
27    film is about 0.5-2.0 cm long, in order for it to  
28    remain within the main pulmonary artery trunk. The  
29    film could be fixed around the catheter starting at  
30    about 4-5 cm from the tip, and in the case of a PVC

1 catheter body, the PVC film heat transfer device  
2 could be bonded by solvent.

3  
4 Such a heat transfer device could be adapted to fit a  
5 catheter less than 7F diameter (2.3mm). More  
6 preferably the heat transfer device can be  
7 incorporated in a catheter of 3-5F (1-1.67mm)  
8 diameter. The heat transfer device should not  
9 increase the outer diameter of the catheter more than  
10 about 0.3F (0.1mm).

11  
12 Using the same technique, a similar film could be  
13 formed purely for temperature sensing. The  
14 temperature sensing material could be deposited on a  
15 backing film, followed by parylene (and gold)  
16 coatings. Such a temperature sensor could be  
17 positioned to 2-4 cm proximal to the heat transfer  
18 device. Optionally a further layer of parylene C or  
19 other insulation is added as the outer layer.

20  
21 According to another embodiment of the present  
22 invention, the heat transfer device is disposed onto  
23 the catheter wall by any known method of deposition,  
24 eg plasma deposition, printing, electroplating onto  
25 plastic, photo lithography etc. Application by  
26 printing uses eg conductive ink, or a conductive  
27 layer, with subsequently etching. This method of  
28 deposition can use any suitable resistive material.  
29 In addition, the temperature sensor material could be  
30 similarly applied.

31

1 According to a second aspect of the present  
2 invention, there is provided a catheter having a  
3 length of its outer wall formed wholly, substantially  
4 or partly from doped material able to act as a heat  
5 transfer device upon application of power  
6 therethrough.

7  
8 This form of heat transfer device could be formed as  
9 an inherent part of the catheter wall, rather than as  
10 a separate addition of a heat transfer device to the  
11 catheter. The catheter wall is sufficiently doped  
12 with a resistive material or ingredient able to pass  
13 electrical current therethrough, without affecting  
14 its other properties. Any conductive material could  
15 be suitable, eg silver, gold.

16  
17 According to a third aspect of the present invention,  
18 there is provided a catheter wall having one or more  
19 metal wires therethrough.

20  
21 By locating the electrical connections within the  
22 catheter body wall, separate lumens for electrical  
23 connections to its distal end within the catheter  
24 interior are no longer required. These wires can  
25 also provide the catheter with the desired or  
26 required stiffness.

27  
28 The wire(s) can be formed from any suitable metal, eg  
29 copper. Preferably, each wire is co-extruded within  
30 the catheter body.

31

1 More preferably, there are one or more sets of  
2 electrical wires in the catheter wall, each set  
3 having the required number of wires for the desired  
4 operations.

5  
6 In one embodiment of the present invention, the  
7 catheter body has three sets of wires, each set  
8 comprising two wires. One set of wires is for a  
9 heating element, and the other two sets are for each  
10 of two temperature sensing elements located on or  
11 along the catheter wall, or one set for measuring  
12 ambient blood temperature, and the other set for  
13 measuring the temperature of the heat transfer  
14 device, or any other suitable combination of  
15 measurements.

16  
17 The wire or wires inside the catheter wall should be  
18 easily exposable and thus connectable to the required  
19 electrical units to which they correspond. Any  
20 exposed wire could be covered by a suitable insulator  
21 such as vinyl adhesive, or urethane potting compound.

22  
23 An example of this aspect of the present invention is  
24 shown in Figure 2 of the accompanying drawings.

25  
26 According to a preferred embodiment of the present  
27 invention, there is provided a catheter combining the  
28 first and third aspects described above.

29  
30 One advantage of the use of one or more aspects of  
31 the present invention as described above is the

1 ability to reduce the size of the catheter, more  
2 particularly for paediatric use. A catheter wherein  
3 the electrical wires required for the heat transfer  
4 device, etc are co-extruded within the catheter body,  
5 means that the catheter may only need a single distal  
6 lumen, (possibly 0.5-0.7 mm diameter) for solution  
7 infusion and pressure monitoring.

8  
9 The novel apparatus and methods of the present  
10 invention could also be used in non-medical fields  
11 using heat transfer devices at or near the distal  
12 ends of elongate tubing to be located in remote  
13 locations. Such fields include aeronautics, any  
14 fluid flow analysis, food and drink processing and  
15 monitoring, water and sewerage management, chemical  
16 engineering, fuel supply to engines, etc.

17  
18 The present invention is also particularly applicable  
19 to the paediatric catheter field.

20  
21 Embodiments of the present invention are shown by way  
22 of example only in the accompanying diagrammatic  
23 drawings in which:

24  
25 Figure 1 is side view of a paediatric catheter;

26

27 Figure 2 is a radial cross-sectional view of a  
28 catheter wall having electrical wires located  
29 therein;

30



1 Figure 3 is an example of a heat transfer device film  
2 for application around a catheter body;

3

4 Figure 4 is an example of a temperature sensor for  
5 application around a catheter body.

6

7 Figure 5 is a longitudinal cross-sectional view of a  
8 catheter body having a heat transfer device  
9 therearound.

10

11 Figures 6a, b and c show a method of preparing a  
12 catheter having a heat transfer device.

13

14 The dimensions referred to in relation to  
15 accompanying diagrammatic drawings are illustrative  
16 only, and in no way limiting or essential.

17

18 Referring to the drawings, Figure 1 shows the general  
19 form of a paediatric pulmonary artery catheter, which  
20 may be 70-100 cm long. At one end, such catheters  
21 generally have a connection 2, for example, to a  
22 TRUCCOM™, and a distal lumen 4. Such catheters are  
23 generally 3-5F size, i.e. approximately 1-1.67mm  
24 diameter.

25

26 For all such catheters, the heat transfer device  
27 should preferably be in the range 0.5-2.0 cm long in  
28 order to remain within the main pulmonary artery  
29 trunk. The catheter body shore hardness should be  
30 about 45-55D for proper handling during insertion

1 into patients. Use of softer materials may be  
2 possible, but may require the additional use of a  
3 wire to stiffen the catheter body allowing  
4 manoeuvrability during insertion.

5  
6 In the versions of the present invention based on the  
7 layering or coating of the transfer device onto or  
8 into the catheter wall, the heat transfer device  
9 should not increase the outer diameter of the  
10 catheter more than 0.3F (0.1mm).

11  
12 Figure 1 shows a schematic representation of a heat  
13 transfer device 6 according to the present invention  
14 2cm long, and located 4cm from the end of the  
15 catheter. Thereafter is located a temperature sensor  
16 8, approximately 0.3cm long.

17  
18 Figure 2 is a cross-section of a catheter wall 10  
19 wherein six copper wires 12 are co-extruded with the  
20 catheter body so as to be located in the catheter  
21 wall 10. Of the six wires, two are located for the  
22 heating element, and two for each of two temperature  
23 sensing elements (not shown). Thus, the catheter  
24 only has a single distal lumen 14, 0.5mm diameter for  
25 solution infusion and pressure monitoring.

26  
27 Figure 3 is an example of a flexible metal film heat  
28 transfer device 20 according to the present  
29 invention. The film consists of a thin high  
30 resistance metal film, e.g. of nickel, chromium or  
31 nickel-chromium, deposited on a PVC film 22, e.g. of

1 25-50 microns thick. The resistor wire 24 in Figure  
2 3 can be patterned using a photolithography mask.  
3 The device 20 includes temperature sensor leads 26.

4  
5 Figure 4 shows a possible pattern for temperature  
6 sensor leads 30 on a similar PVC film 32 to act as a  
7 temperature sensor as shown in Figure 1. It is  
8 similarly made to the device in Figure 3, but only  
9 the temperature sensing material is deposited  
10 followed by Paralyene C and gold coatings.

11  
12 Figure 5 shows a longitudinal cross-section of a  
13 catheter having a heat transfer device 34 based on  
14 that shown in Figure 3. Around the catheter body 36  
15 is a PVC film 0.05mm thick. The resistor and  
16 temperature sensor leads are on the PVC film, which  
17 is then coated with a suitable insulator such as  
18 Parylene C, possibly of 0.005mm thickness. The outer  
19 surface is coated with a silver or gold layer  
20 (suitably 5-10 microns thick).

21  
22 As shown in Figures 6a-6c the overall heat transfer  
23 device 34 can be conjoined with the catheter body 36  
24 using any suitable means such as a solvent. A  
25 temperature sensor 40 such as that shown in Figure 4  
26 is also conjoined with the catheter body 36, e.g. 2-4  
27 cm proximal to the device 34. Thereafter, and as  
28 shown in Figures 6a-c, the wires 38 inside the  
29 catheter wall 36 are then exposed and the heat and  
30 temperature sensing wires are then connected and

1 covered by a vinyl adhesive or another suitable  
2 insulator.

3

4

1     Claims

2

3     1.     A catheter having a heat transfer device at or  
4           near its distal end, wherein the heat transfer  
5           device is layered or coated onto or into the  
6           catheter wall.

7

8     2.     A catheter as claimed in Claim 1 wherein the  
9           heat transfer device is a flexible film having  
10          one or more electrical resistor flow paths  
11          thereon or therethrough, which film is locatable  
12          around the catheter wall.

13

14    3.     A catheter as claimed in Claim 2 wherein the  
15          film is a flexible metal film on which the one  
16          or more electrical paths have been etched or  
17          otherwise created.

18

19    4.     A catheter as claimed in Claim 2 wherein the one  
20          or more electrical paths are added onto a  
21          plastic film backing.

22

23    5.     A catheter as claimed in Claim 4 wherein the one  
24          or more electrical paths are added by a  
25          deposition process.

26

27    6.     A catheter as claimed in Claim 4 wherein the one  
28          or electrical paths are added by a coating  
29          process.

30

- 1       7.    A catheter as claimed in Claim 1 wherein the  
2           heat transfer device is disposed directly onto  
3           the catheter wall.  
4
- 5       8.    A catheter as claimed in Claim 7 wherein the  
6           heat transfer device is disposed onto the  
7           catheter wall by a deposition process.  
8
- 9       9.    A catheter as claimed in Claim 8 where in the  
10          deposition process is a plasma deposition  
11          process.  
12
- 13      10.   A catheter as claimed in Claim 8 wherein the  
14          deposition process is a printing process.  
15
- 16      11.   A catheter as claimed in Claim 10 wherein the  
17          printing process uses a conductive ink or a  
18          conductive layer, with subsequent etching.  
19
- 20      12.   A catheter as claimed in any one of Claims 7-11  
21          wherein a temperature sensor material is also  
22          disposed onto the catheter wall by a deposition  
23          process.  
24
- 25      13.   A catheter as claimed in any one of the  
26          preceding Claims wherein the heat transfer  
27          device includes one or more temperature sensors  
28          or sensor leads.  
29

- 1      14. A catheter as claimed in any one of the  
2          preceding Claims wherein one or more insulator  
3          layers are located over the resistor structure.  
4
- 5      15. A catheter as claimed in Claim 14 wherein one of  
6          the insulator layers is parylene C.  
7
- 8      16. A catheter as claimed in any one of the  
9          preceding Claims wherein the heat transfer  
10        device comprises an outer or penultimate outer  
11        layer of silver or gold.  
12
- 13     17. A catheter as claimed in Claim 1 wherein a  
14        length of the outer wall of the catheter is  
15        wholly, substantially or partly formed from  
16        doped material able to act as a heat transfer  
17        device upon application of power therethrough.  
18
- 19     18. A catheter as claimed in Claim 17 wherein the  
20        doped material is silver or gold.  
21
- 22     19. A catheter wherein the catheter wall has one or  
23        more metal wires therethrough.  
24
- 25     20. A catheter as claimed in Claim 19 wherein the or  
26        each wire is copper.  
27
- 28     21. A catheter as claimed in Claim 19 or Claim 20  
29        wherein the or each wire is co-extruded within  
30        the catheter body.  
31

- 1      22. A catheter as claimed in any one of Claims 19-21  
2            wherein the catheter wall includes one or more  
3            sets of wires.  
4
- 5      23. A catheter as claimed in Claim 22 wherein the  
6            catheter body has three sets of wires, each set  
7            comprising two wires.  
8
- 9      24. A catheter as claimed in any one of Claims 19-24  
10            wherein they or each wire inside the catheter  
11            wall is easily exposable.  
12
- 13     25. A catheter as claimed in any one of Claims 1-18  
14            in combination with a catheter as claimed in any  
15            one of Claims 19-24.  
16
- 17     26. A catheter as claimed in any one of the above  
18            Claims of size 3-5F.  
19
- 20     27. A catheter as claimed in any one of the  
21            preceding Claims having a single distal lumen.  
22
- 23     28. A catheter as claimed in Claim 27 wherein the  
24            lumen has a diameter of approximately 0.5-07 mm.



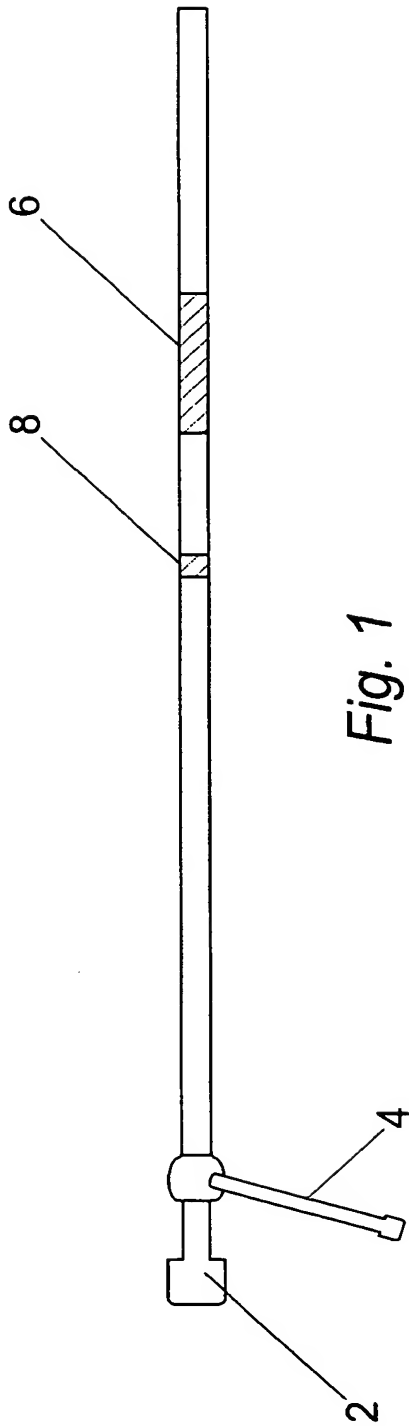


Fig. 1

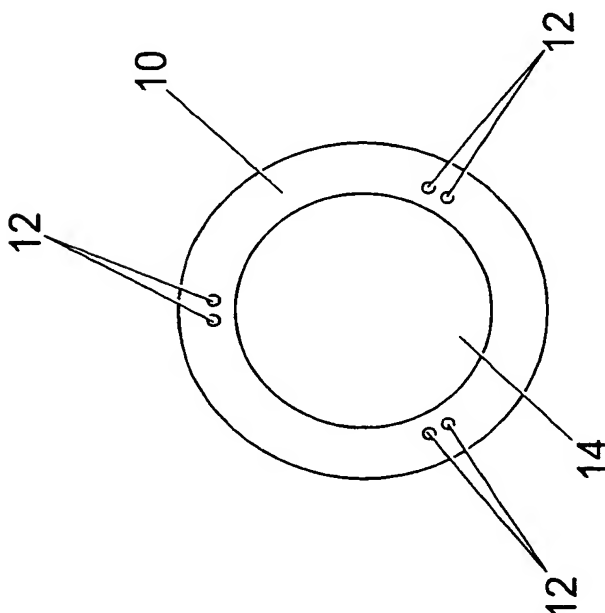


Fig. 2

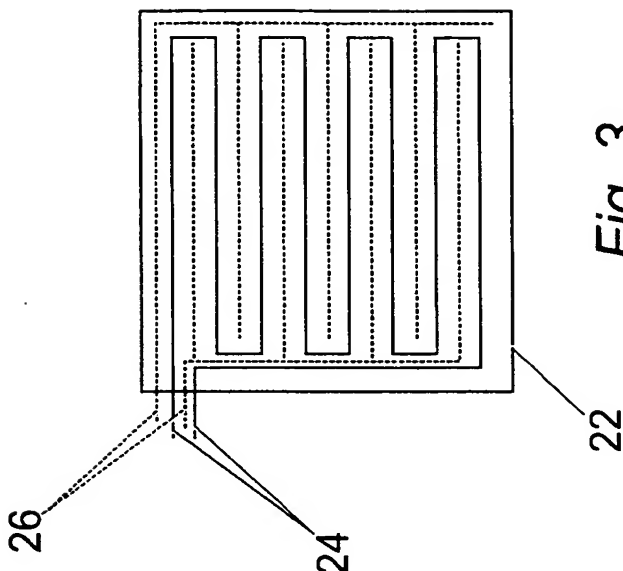
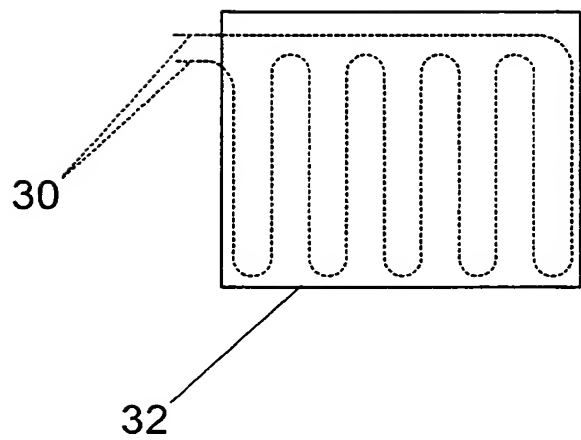
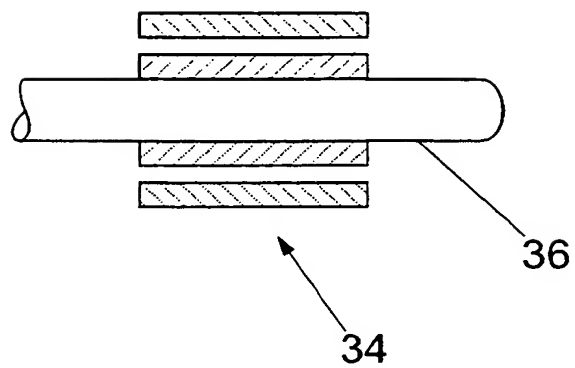
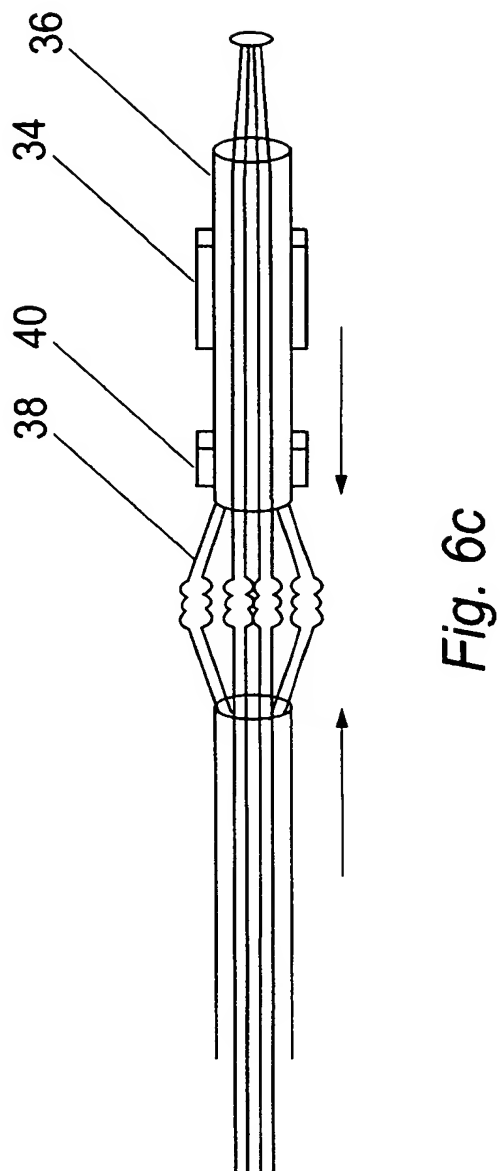
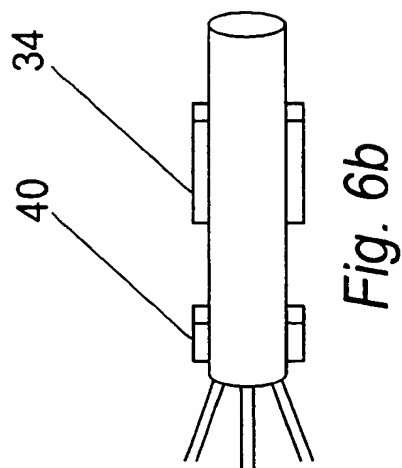
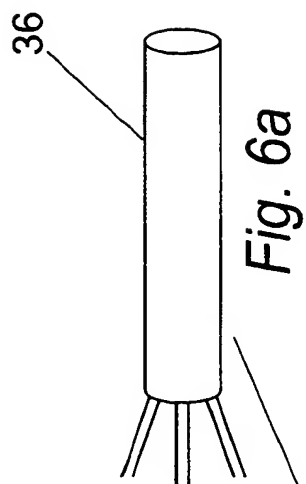


Fig. 3

2 / 3

*Fig. 4**Fig. 5*

3 / 3



# INTERNATIONAL SEARCH REPORT

Inter. Application No  
PCT/GB 00/03273

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B18/08

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 720 775 A (LARNARD DONALD J) 24 February 1998 (1998-02-24)	1-3,5-9, 16-18
Y	column 3, line 11 -column 5, line 18; figures	25
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A	US 5 380 320 A (MORRIS JAMES R) 10 January 1995 (1995-01-10) abstract; figures	1,14,15
A	US 5 921 924 A (AVITALL BOAZ) 13 July 1999 (1999-07-13) claim 8; figures	1,7,8
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
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- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*8\* document member of the same patent family

Date of the actual completion of the international search

16 January 2001

Date of mailing of the international search report

23. 01 2001

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# INTERNATIONAL SEARCH REPORT

Inter. Application No  
PCT/GB 00/03273

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 865 801 A (HOUSER RUSSELL A) 2 February 1999 (1999-02-02) abstract; figures ----	1
X	US 5 247 136 A (MITSUYASU KAZUYUKI ET AL) 21 September 1993 (1993-09-21) column 3, line 4 -column 5, line 9; figures ----	19-22, 24,26-28 25
Y		
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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/GB 00/03273

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-18

A catheter having a heat transfer device near its distal end, wherein the heat transfer device is layered or coated onto the catheter wall.

2. Claims: 19-28

A catheter having one or more metal wires through the catheter wall.

# INTERNATIONAL SEARCH REPORT

Inter: Application No

PCT/GS 00/03273

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